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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,471	06/25/2003	Abram Katz	13425-115001 / BV-1025	3516
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FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER WOOD, AMANDA P	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,471	Applicant(s) KATZ ET AL.	
	Examiner Amanda P. Wood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>25 June 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 1-8 in the reply filed on 17 November 2005 is acknowledged.

Claims 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 November 2005.

Claims 1-8 are presented for consideration on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what Applicant means by the term "candidate" in line 3 of Claim 7 (i.e., whether the term refers to a candidate agent or to something else). The Examiner will treat the term "candidate" as meaning "candidate agent" as recited in Applicant's previous claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birnbaum et al (US 5,932,417) in view of Levy et al (Am. J. of Med. 1994) and in view of Draznin et al.

Methods for identifying an agent that modulates glucose uptake in a mammalian cell are claimed.

Birnbaum et al teach methods for controlling capacitative calcium entry (i.e., CCE, store-mediated calcium entry, or SMCE) in a mammalian cell, wherein compounds and other agents are screened to determine if they are useful in controlling CCE. For example, the screening method involves exposing the cell to a potential drug or other compound and determining if the level of trp protein (i.e., a store-mediated calcium entry-regulating factor) is reduced, thereby reducing (i.e., modulating) calcium ion entry into the cell. Furthermore, Birnbaum et al specifically teach that not only agents that block calcium entry due to trp expression but also agents that stimulate calcium entry due to trp can be screened in this way (see, for example, col. 15, lines 5-60, and col. 16, lines 1-40).

Birnbaum et al do not specifically teach a method of determining whether a candidate agent modulates or increases capacitative calcium entry into a cell in addition

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to determining whether an agent modulates or increases glucose uptake into a cell or that measures glucose uptake into a cell.

Draznin et al beneficially teaches that intracellular calcium concentrations may exert a dual role in the regulation of cellular sensitivity to insulin, wherein a minimal concentration of intracellular calcium must exist to promote insulin action and also an increased level of intracellular calcium may provide a critical signal for decreased insulin action. Draznin et al further teach that it is possible that intact calcium ion fluxes in and out of cells may be required to maintain an optimal rate of glucose transport. In addition, Draznin et al teach that increased concentrations of intracellular calcium deactivated calcium channels and reduced the rate of calcium flux. Therefore, Draznin et al beneficially teach that if maintenance of calcium flux is required to optimize glucose transport, then deactivation of this process by high and/or sustained intracellular concentrations of calcium may result in a decrease of insulin-stimulated glucose transport (see, for example, Abstract, and pg. 14388, col. 1, pgh. 3, and col. 2).

Levy et al beneficially teach that abnormal intracellular calcium homeostasis is a common defect in both type I and II diabetes. For example, Levy et al teach that increased intracellular calcium is the most common finding in both types of diabetes, and impairs the cell's ability to generate acute calcium signals, which may impair insulin action and lead to insulin resistance. Furthermore, Levy et al teach that intracellular calcium has an optimal range for mediating insulin action (e.g., chelation of intracellular calcium prevents insulin-stimulated glucose transport, whereas sustained elevation in intracellular calcium levels decreases insulin-stimulated glucose uptake). In addition,

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Levy et al beneficially teach that abnormal intracellular calcium homeostasis is a common link that contributes to the various manifestations of the diabetic disease process, including metabolic, cardiovascular, ocular, and neural manifestations.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Birnbaum et al based upon the beneficial teachings provided by the secondary references with respect to the art-recognized importance of intracellular calcium levels to glucose transport.

Furthermore, the cited references particularly point out that maintenance of calcium flux in cells may be a requirement for optimal glucose transport and that it would be beneficial to explore for compounds that can control capacitative calcium entry, and therefore, it would have been obvious and beneficial for the skilled artisan to use the methods taught by Birnbaum et al so as to test candidate agents to determine whether they can modulate or increase capacitative calcium entry, and thereby modulate or increase glucose uptake. The result-effective adjustment of particular conventional working conditions (e.g., testing a candidate agent with a particular store-mediated calcium entry-regulating factor, measuring glucose uptake in a particular manner, or using a particular method of monitoring capacitative calcium entry) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of

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ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. P. Wood
Examiner
Art Unit 1655

APW



CHRISTOPHER R. TATE
PRIMARY EXAMINER